

## NCRO HIGHLIGHTS

**Duke  
Neuroscience**

### Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



July 2008

*The mission of the NCRO is to foster the development of a world-class neuroscience clinical trials center.*

#### Who's Who in the NCRO

Management	Coordination	Email:
Mark Stacy, Medical Director	Kate Beck 668-2278	<a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>
Ron Beauvais, Administrator	Joanne Field 668-2842	<a href="mailto:joanne.field@duke.edu">joanne.field@duke.edu</a>
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Cathy O'Neill, Finance Manager	Sarah Wyne 668-2837	<a href="mailto:sarah.wyne@duke.edu">sarah.wyne@duke.edu</a>

#### ACTIVE ENROLLING STUDIES

The NCRO currently supports **39** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

#### EPILEPSY

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-7/31/08
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 5
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	5-6 / 0

#### GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	5 / 3
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#### MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 91
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 25
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 5
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharmaceuticals	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 1
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 0
STACY, Mark	Schering Plough	Moderate-to-severe PD	SCH420814 (P04501)	Perry-Trice 684-0865	5-6 / 4
STACY, Mark	Novartis	Non-motor symptoms in idiopathic PD	CELC200AUS14 (Stalevo vs. IR carbidopa/levodopa	Field 668-2842	8 / 0
STACY, Mark	Weill Cornell	Parkinson's Disease	Coenzyme Q10 (QE3)	Field 668-2842	12 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	8-10 / 6
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#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Field 668-2842	45 / 38
GOLDSTEIN, Larry	Schering Plough	Atherosclerotic Disease	SCH 530348 with standard of care (TRA 2°P – TIMI 50)	TBD	75 / 0
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 5
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 2
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 815
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

#### NON-NCRO TRIALS

MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 0
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\*\*\*STUDY SPOTLIGHT\*\*\*

**New Approved Studies Ready for Recruitment!!**  
Please see further details below – Thank you for your Support!

**L. Goldstein (PI) – Schering Plough (TRA 2°P – TIMI 50)**

**“A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects With a History of Atherosclerotic Disease: Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events”**

The primary objective of this study is to evaluate the hypothesis that SCH 530348 added to standard of care will reduce the incidence of atherothrombotic ischemic events relative to standard of care alone, as measured by the composite of cardiovascular death, myocardial infarction, stroke and urgent coronary revascularization. Eligible subjects (at least 18 years of age with an acute, presumed thrombotic stroke identified based on review of admissions to the Duke Neurology service) meeting all eligibility criteria will be recruited. Subjects will be randomized to one of two regimens (in addition to standard of care for stroke patients): SCH 530348 2.5 mg daily or matching placebo. Trial participation for subjects will include up to 12 months of study drug dosing, then return every 6 months thereafter for efficacy/safety evaluations until the end of the study (once a statistically defined number of efficacy endpoint events have been observed) and includes allowing each subject participation for at least one year. The study is expected to recruit 20,000 subjects. We anticipate recruiting 75 subjects at DUHS. You may contact Dr. Larry Goldstein (684-3801) for more information about this study.

**M. Stacy (PI) – Weill Medical College of Cornell University (QE3)**

**“Effects of Coenzyme Q<sub>10</sub> in Parkinson Disease”**

The primary objective of this study is to assess the effects of two dosages of CoQ on slowing the progression impairment of Parkinson disease in early, otherwise untreated subjects, as measured by the total score on the Unified Parkinson Disease Rating Scale (UPDRS). Eligible subjects (aged 30 or older with early Parkinson disease who have not yet developed sufficient disability to require dopaminergic agent treatment) meeting all eligibility criteria will be randomized to one of three regimens: CoQ 1200 mg with vitamin E 1200 IU/day; CoQ 2400 mg with vitamin E 1200 IU/day or matching placebo with vitamin E 1200 IU/day. Trial participation for subjects will last approximately 16 months plus a 30 day screening period. The study is expected to recruit 600 subjects. We anticipate recruiting 12 subjects at DUHS. You may contact Dr. Mark Stacy or Joanne Field (668-2842) for more information about this study.

**Duke University School of Medicine  
Clinical Research Support Office (CRSO)  
LUNCH AND LEARN SERIES**

**Lunch and Learns are held the 2nd Monday of each Month**

Time: Noon - 1:00 pm

**NEW LOCATION:** School of Nursing

Room 1014 (Peter and Ginny Nicholas Auditorium and Learning Center)  
307 Trent Drive

No registration necessary

Beverages and desserts are provided. Please feel free to bring your lunch.

**Scheduled Topics:**

**September 8, 2008**

**Topic: Regulatory Requirements of Anonymous and Decedent Research**  
**Presenter: Lawrence Muhlbaier, Ph.D.**  
**Assistant Professor, Duke University**

If you have questions, please contact the CRSO at [CRSO.Help@notes.duke.edu](mailto:CRSO.Help@notes.duke.edu) or 681-6665.

**We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: JoAnn Jones @ [jones018@mc.duke.edu](mailto:jones018@mc.duke.edu).**